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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/675,950 09/29/00 JORGENSEN J 6136.200-US **EXAMINER** 025908 HM22/0619 NOVOZYMES NORTH AMERICA, INC. OZGA, B C/O NOVO NORDISK OF NORTH AMERICA, INC. ART UNIT PAPER NUMBER 405 LEXINGTON AVENUE, SUITE 6400 NEW YORK NY 10174 1651 **DATE MAILED:**

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

06/19/01

	_•		Application No.	Applicant(s)								
•	Office Action Summary		09/675,950	JORGENSEN ET AL.								
			Examiner	Art Unit								
	<u> </u>		Brett T Ozga	1651								
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply											
	A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any Status											
	1)	Responsive to communication(s) filed on										
	2a) <u></u> □		 s action is non-final.	•								
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.											
	Dispositi	Disposition of Claims										
	4)🖂	Claim(s) <u>1-8,11-15 and 17-28</u> is/are pending in	the application.									
		a) Of the above claim(s) is/are withdraw										
		Claim(s) is/are allowed.										
6)⊠ Claim(s) <u>1-8,11-15 and 17-28</u> is/are rejected. 7)□ Claim(s) is/are objected to.												
							8)[Claims are subject to restriction and/or of				
	Application	on Papers										
	9) 🔲 -	9) The specification is objected to by the Examiner.										
		10) The drawing(s) filed on is/are objected to by the Examiner.										
11) The proposed drawing correction filed on is: a) approved b) disapproved.												
12) ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) ☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).												
							a)[∑	a) ☑ All b) ☐ Some * c) ☐ None of:				
							1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No											
Copies of the certified copies of the priority documents have been received in this National Standard application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.												
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).												
I	<u> </u>	,- <i>,</i> -										
-	tachment(s											
1	\	of References Cited (PTO-892)	40) 🗖									
_	1 ☐ Notice 1 ☐ Inform	of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u>	18)	(PTO-413) Paper No(s) atent Application (PTO-152)								
v.s PŢ	O326 (Rev.	omark Office O1-01) Office Action	n Summary	Part of Paper No. 6								

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether the first and second "biomass" refer to the same biomass or two different biomasses, therefore clarification in each of the four claims is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-8, 12-15, 19-21, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker (WO 91/06638).

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The instant application's first independent claim is a process for preparing an enzyme containing particle comprising spray drying a fermentation broth starting material to obtain a solid particle. The second independent claim is a process for preparing an enzyme containing particle also comprising a process selected from granulation and coating. The third independent claim is the particle itself.

Becker teaches process for preparing an enzyme-containing particle comprising spray drying a fermentation broth starting material to obtain a solid particle. Becker also teaches a process for preparing an enzyme containing particle comprising coating. (See abstract.)

Becker teaches the process wherein the biomass constitutes at least 90% of the biomass originating from the fermentation. They also teach the process using a fermentation broth. (See p.4, b))

He teaches using inorganic salts and clays as an additive. (See p. 6, second paragraph)

He teaches heating the starting material to 44oC and the starting material containing at least 3mg active enzyme protein per liter. (See p. 10, second paragraph)

He teaches the starting material having a viscosity of 10-5000 cps. (See p. 7)

He teaches atomizing. (See p. 11.)

He teaches drying in a fluid bed dryer. (See claim 1 a))

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 11-15,17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker in view of Worts et al. (GB 1483591) and Liddell et al. (EP 0366303).

Becker teaches process for preparing an enzyme-containing particle comprising spray drying a fermentation broth starting material to obtain a solid particle. Becker also teaches a process for preparing an enzyme containing particle comprising coating. (See abstract.)

Becker teaches the process wherein the biomass constitutes at least 90% of the biomass originating from the fermentation. They also teach the process using a fermentation broth. (See p.4, b))

He teaches using inorganic salts and clays as an additive. (See p. 6, second paragraph)

He teaches heating the starting material to 44oC and the starting material containing at least 3mg active enzyme protein per liter. (See p. 10, second paragraph)

He teaches the starting material having a viscosity of 10-5000 cps. (See p. 7)

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He teaches atomizing. (See p. 11.)

He teaches drying in a fluid bed dryer. (See claim 1 a))

Becker et al. do not teach prilling, nor do they teach hydrolases.

Worts et al. teaches the process wherein the enzyme particles have been granulated by prilling.

Liddell et al. teaches the process wherein the enzyme is a hydrolase. (See abstract.)

Though not expressly taught in the above, given the prior art, it would be obvious to choose the microorganism from any one listed in claim 2, especially since it is the enzyme not the microorganism itself that is ultimately desired.

Also, though sterilization and desludging are not expressly taught, it would be obvious to remove impurities for the benefit of having a cleaner final product.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the process of Becker et al. by the addition of the prilling of Worts et al. and the hydrolase of Liddell et al. to gain the known and disclosed advantages of better granulation via prilling and wider applicability by choosing the broader class of hydrolases. Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have practiced the process as recited in the claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

BTO June 15, 2001

> LEON B. LANKFORD, JR. PRIMARY EXAMINER